

Application No: 10/623,933

EQ 098560188 US

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Applicant: James C. Smith

REMARKS

The Office Action of May 5, 2006, has been received and considered. A Petition for Extension of Time with appropriate fee is filed with this response. Claims 18-23 and 47-58 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Smith US 5,513,768, in view of Carluccio US 4,390,298 in view of Leopardi et. al. US 5,514,339.

It should be noted that the present inventor, James C. Smith, is the same inventor of Patent Numbers US- 5,295,599 and US-5,513,768 and US-6,145,688 and US-6,375,028 and US-6,622,882 as noted in the attached Notice of References Cited by the examiner.

As stated in my Patent application "Another area of this application relates to the wiping mechanism which was described in my Invention Disclosure "Screw Cap with Sealing/Wiping Diaphragm" date February 11, 1994 and a second version dated and filed January 11, 1996 Disclosure Doc. 390080 with the Patent Office. " Applicant enclosed front page of each recorded document for reference. In the discussion of obviousness, applicant wanted to relate to the examiner, that applicant had invented the wiper embodiment many years prior to the patent issue dates of both Smith and Leopardi which both issued on May 7, 1996. I state this for reference only but also to suggest that it would not have been obvious to combine these 2 embodiments used in the medical field with an embodiment by Carluccio that is used in cosmetic industry for the purpose of applying mascara.

It is also noted that the present invention adds additional features to caps solving an unrecognized problem in the liquid handling field producing new and unexpected results.

By this response, Claims 18 and 47 are amended. Minor corrections have been made to the specification. No new matter has been introduced. Reconsideration of the application as amended is respectfully requested.

Summary of Invention

There has been a very serious unrecognized problem in the use of hand held liquid handling pipetters in the transportation of calibrated amounts of fluid samples from one location to another for testing or evaluations in laboratory use for many years. In the transfer of the fluid samples, the residue or non-calibrated fluid attaches itself to the outside surface of the plastic disposable conical shaped pipette tip. This long felt problem has been address by prior inventions such as adding silicon to the polypropylene material that the pipette tips are manufactured from. The additional silicon is meant to reduce the surface tension between the fluids dispensed and the plastic material of the pipette tip. This method has added additional cost to the manufacturing of the tips and in most cases has proved ineffective.

The present invention relates to a wiping cap specifically engineered to be accessed with a plastic disposable pipette tip that is attached to a precision hand held air-displacement pipetter used in the liquid handling industry. **The pipetter is created with volume selection for transferring calibrated fluid samples from 1.0uL to 5.0mL with accuracy ranging from +/- 0.6 to 2.0% and reproducibility of 0.2 to 0.5%** from one location to another for testing or evaluation unlike that of a syringe which is used for accessing body fluids as described in Leopardi US 5,514,339.

The pipetter includes a barrel (61) and a suction device which is in communication with the barrel for drawing up to a first volume of calibrated fluid (119) into the pipette tip (115). The pipette tip includes a pipette tip body defining an interior frustum shaped cavity (124) having an apex end (114) for receiving the fluid drawn in by the pipetter, and an upper portion for attachment to the pipetter in a fluid tight relationship. This plastic conical shaped disposable pipette tips outer surface (125) is very important in the development of the specifically engineered conical shaped wiper finger (90) of the wiping cap. These wiper fingers (90) rotate more than one revolution and are formed from a substantially closed apex end (114) of the conical wiper section.

In normal operation when the frustum shaped pipette tip (115) is inserted into the fluid (41) of a sample filled container (50) and the calibrated precise amount of sample (119) is drawn inside the frustum shaped tip cavity (124) for transportation to another location, there exists a thin film or droplets of non-calibrated residue fluid (116) attached to the outside surface (125) of the frustum shaped pipette tip. This is due to the surface tension of the material used to manufacture the pipette tip (i.e.: polypropylene, polyethylene etc.) and the characteristic of the fluid sample that is being transferred by the air-displacement pipettor. The thin film (116) that is left on the outside (125) of the frustum shaped plastic pipette tip usually combines to form small fluid droplets (116) and can produce these **Unrecognized Problems**:

- Affect the accuracy of the calibrated sample if they combine with the precise calibrated volume that is being dispensed from the inside of the pipette tip cavity
- Droplets can fall from the outside surface of the pipette tip while being transported in or out of the container;
- Droplets can migrate to the pipette tip's dispensing end and combine with the precision amount of internal calibrated fluid to affect the dispensing accuracy;
- Leads to cross-contamination or contamination in general, if any of the outside fluid were to contact any surface or thing (i.e. radioactive material or volatile fluids);
- Very small and precious any additional fluid that would be wasted by being attached to the outside surface of the pipette tip could become very costly and would allow fewer test specimens to be examined.

Applicant's invention addresses all of these unrecognized problems by providing a one piece injection molded conical wiping finger closure. These fingers, while wrapping themselves about the conical frustum shaped outside surface of the pipette tip, create a squeegee like wiper as the conical pipette tip enters and is withdrawn from a container or vial. The wiper, as part of the sealable device, is specifically engineered to eliminate any and all residue attached to the outside surface of a pipette tip that typically occurs during transferring of fluids from a sample fluid container during liquid pipetting.

The wiping device in the two-cap design is created with the **spiral wiping fingers 90** rotating **more than one full revolution and converging to the substantially closed apex end 113** unlike that of Carluccio. The spiral wiping fingers 90 are formed from at least one helical slot 112 beginning at a substantial closed apex end 113 as shown in Figure 12 and molded into the wiping cap 92 attached to the container tube 50 by a hinge 94. Locking Cap 96 is molded 180

degrees opposite the wiping cap 92 and is connected to tube 50 by hinge 98, which completes the one-piece injection molded assembly. In use the tube 50 would be filled with fluid 41, wiper cap 92 would then be rotated into the tubes tapered sealing surface 100 mating with the wiping cap 92 sealing surface 102. To access the tubes fluid with a pipette tip 115 attached to pipetter barrel 61, you would pass the tip 115 through the **substantially closed** spiral wiping finger or fingers 90, by expanding them, draw the calibrated sample fluid 119 into the cavity 124 of pipette tip 115, withdraw the tip 115 from the tube 50 and transport the sample 119 to its location for its dispensing. This residue fluid is then left within tube 50 as shown in Figure 16 and Figure 17.

Unlike Carluccio, the applicant's wiper section includes wiper fingers 90 that are engineered to wrap about the pipette tip 115 more than one revolution. **As shown in Figure 12 which is a top view of Figure 11, the wiper fingers 90 are created with 2 helical slots 112, each slot rotates about the substantial closed apex end 113 two and one-half revolutions as shown in the relaxed or as molded condition.** This is very important to insure that in all cases, even when large conical shaped pipette tips are used, that the wiping fingers 90 are engineered to wrap a minimum of one full revolution to ensure the entire surface 125 is encapsulated by the wiping finger 90. This is necessary to insure the squeegee like design of the fingers can complete a 360 degree plus cleaning of the conical pipette tip 115 outer surface 125.

In addition, the substantial closed end 113 insures that when a small pipette tip with a pin – point dispensing end is inserted into the conical wiper section, that the wiper fingers 90 will removed in a squeegee like action all non-calibrated residue fluid droplets 116 from the entire outside surface 125 of the tip 115. This includes any droplets being created by the squeegee like action of the wiper fingers 90 moving downward over the outside surface 125 of the tip to insure any and all residue is squeegee into the container 50, including droplets attached to apex end 114. This is of the utmost importance sense the action of the wipers will increasingly turn the residue film into droplets as the pipette tip is axially withdrawn until the fluid reaches apex end 114, at which time the residue fluid will be wiped clean as the substantial closed apex end 113 wraps itself about the dispensing end 114 of the pipette tip 115 removing the last droplet as the tip is withdrawn.

Assuming a pipette tip was installed in Carluccio wiper plug, as the office action suggest, the

wiping structure lacks the capability to provide more than one full revolution of a wiping finger as required in the applicants invention. In addition, Carluccio is also not created to remove all the residue fluid which is attached to a conical shaped pipette device tapering to a very small pinpoint dispensing ends that are necessary for the delivery of fluids in the pipetting field. Thus, as describe and shown in Carluccio, the structure would be particularly ineffective about the small conical dispensing ends of the pipette tips, if a pipette tip was ever installed into said Carluccio wiper cap as the office action suggested.

Therefore, as will be discussed, the features of the applicant's invention are unique and solve many unrecognized problems in the liquid pipetting industry. In addition, the structure of the applicant's invention produces unexpected results that cannot be anticipated by Smith US 5,513,768, Carluccio US 4,390,298 or Leopardi US 5,514,339 nor is there any motivation to combine such references as will be shown below.

The applicants invention solves the above relate problems and provides the unappreciated advantages and benefits associated with the transfer or pipetting of liquids in the laboratories using this new wiper cap design are many and produce new and unexpected results that are not enjoyed by any prior art inventions:

(Page 21, lines 29-32) **Unappreciated Advantages-Unexpected Results**

- Eliminating the necessity to wipe the outside surface of the tip with tissue;
- Reduces contamination associated with pipetting hazardous materials;
- Minimizes potential fluid loss and contamination due to spillage;
- Increases the accuracy and precision of the dispensed sample by eliminating the possibility of outside surface fluid combining with the calibrated interior sample volume;
- Reduces the time required to perform pipetting tasks;
- Saves valuable sample fluids while prolonging sample life and;
- Minimizes air exchanges within the container.

Applicant's new invention addresses all of these concerns by providing an injection molded wiper finger as part of the closure device specifically engineered to eliminate any and all residue attached to the outside surface of a pipette tip that typically occurs during transferring of fluids

from a sample fluid container during liquid pipetting. Applicant's invention therefore is vastly superior to that of Smith '768, Carluccio '298 or Leopardi '339 or any combination thereof.

Discussion of Rejection

Claims 18-23 and 47-58 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Smith US 5,513,768, in view of Carluccio US 4,390,298 in view of Leopardi et. al. US 5,514,339.

Claims 18 and 47 has been amended to recite a wiping cap device for pipette tips, including a conical shaped wiping finger created by a least one helical slot beginning at a substantial closed apex end of the conical wall wiper section. The wiper finger or fingers then rotate more than one revolution about the conical shaped pipette tip includes means for removing the non-calibrated residue fluid attached to the outside surface of said pipette tip during fluid transfer from a container. This amendment was made so that the relationship between the calibrated fluid that the pipetter is transferring and the non-calibrated fluid that inadvertently became attached to the outside surface of the conical shaped pipette tip is clearly and positively recited. In addition, the wiper finger and the apex end of the conical wiping wall section is also clearly recited to insure a substantial closure at the apex end. This is clearly consistent with the restriction requirement for it includes the structure of the wiping cap device which the restriction was based and further limits original claims 18 and 47.

Carluccio – Pat. # 4,390,298

Carluccio discloses a wiper plug for use in a dispenser for liquid cosmetic products that removes excess liquid on the rod and head of a cosmetic applicator when the applicator is withdrawn from the bottle but is designed to leave some amount of fluid, such as mascara or nail polish, on the applicator head to perform a particular function unlike applicants invention. If indeed the wiper removed all of the material from the applicator as is required in the applicant's invention, Carluccio invention would not function for it is the fluid that is left on the brush or the polyurethane foam that allows for the withdrawn applicator head to apply eyelash mascara or nail polish.

In addition, the wiper structure 30 may look similar to applicant's invention but is completely different both in structure and function from the wiper fingers 90 as disclosed in the applicant's application. Carluccio wiping mechanism is directed at a different wiping structure to accommodate the removal of only a portion of the fluid to solve a different type of problem in a completely different field than that of the applicants.

The structure of Carluccio invention relates to the conical wall section that includes a resilient wiper section 30 that is formed as only the lower portion of wiper plug 12 "In the embodiment shown in Fig. 1-2, the wiper plug 12 has a plug body 28, and a wiper section 30 of resilient material that extend axially from the plug body 28" (Page 2, lines 28-31) **As shown in Figs. 1-2, the wiper section 30 is constructed with less than one full rotation of helical slot 34. In fact, the drawings are very clear to present a conical structure that begins at diameter 14a which is the same diameter as that of rod 18, much larger than the head 22 of the applicator that it is attached to. Wiper section 30 is shown in the relaxed or as molded condition since the helical slot 34 has not been expanded.** The helical slot 34 extends upward and rotates about the conical structure $\frac{3}{4}$ of a rotation or 270 degrees forming resilient wiper section 30. As the helical slot extends further upward beyond the resilient portion 30 of the conical surface, the wall sections shown as wiper plug 12 become less resilient because of structural relationship with the plug body 28. The plug body 12 which depend from the plug body 28 would not be flexible as they are solid wall sections not dissected by the helical slot 34. This wall section, wiper plug 12 is not resilient and forms more than $\frac{1}{2}$ of the total conical wall surface unlike that of the applicant's invention.

"A helical slot 34 that extend from the lower edge 32 axially along the wiper section 30 such that the wiper opening 14a defined by lower wiper edge 32 is radially enlargeable. When the applicator 16 is fully inserted, **the wiper edge 32 of the wiper section 30 wraps around and is resiliently held against the rod 18 of the applicator 16.** At the same time, when the applicator is inserted or withdrawn, the opening 14a enlarges to accommodate the larger diameter bristles 22 or other enlarged applicator heads." (Page 2, lines 34-43)

As described, it is only the conical wall section 30 created by the slot 34 that provides means to hold the opening 14a of wiper edge 32 against rod 18. **The fact that the helical slot**

only rotates about the conical surface less than one full turn or 360 degrees insures the fact that the wall section as designed by Carluccio, cannot fully wrap itself about the applicator head as that of the applicants invention.

Additional comparisons between Carluccio and the invention as claimed in claim 18 and 47 readily distinguishes this reference. Again, the specific design of the wiper edge 32 and wiper section 30 of Carluccio is unlike that of the applicant's invention. As shown, the wiper section 30 is conical and terminates in a lower annular wiper edge or rim 32 of enlarged thickness (Carluccio Page 2, lines 31-33). This detail, which performs the wiping, is specifically designed to only rotate less than one full turn around a rod shaped brush and scrape the excess fluid off the brush. **The major portion of the conical wall structure is constructed of wiper plug wall 12 which is not flexible and thus does not add to the resiliency of the conical wall section as suggested in the office action.** In addition, due to the increased wall section of wiper edge 32 as shown in Figure 1, the wiper edge 32 would not be capable of creating an adjustable opening 14a that would be necessary to adapt to the conical configuration that is associated with disposable pipette tips. This is due to the fact that **some conical pipette tips can increase 5 to 10 times their smallest diameter. (i.e.: .025 to .340 Diameters).** This in addition to the fact that the resilient wiper section 30 only forms a partial finger that wraps itself less than one full turn insures that the wiper section could never wrap itself completely about any applicator that is installed into said wiper plug unlike applicant's wiper design.

To further illustrate the differences between Carluccio and the applicants Invention:

- Carluccio's helical formed resilient wiper finger 30 is created with less than one full rotation of helical slot 34 as shown in Figure 1.
- The wiping plug 12 wall section above the wiper section 30 is not flexible or resilient, as stated in the patent, and forms the major portion of the conical wall section in Fig. 1.
- Opening 14a is a large diameter opening which is engineered to adapt to the rod 18 diameter and is not a substantially closed end as is required in applicant's invention.
- The wiper edge 32 is constructed of enlarged thickness to limit the resilient capability of opening 14a. This contradicts the applicant's invention which requires a resilient substantially closed end to insure encapsulation of pin-point dispensing ends.

- Carluccio discloses a wiper plug for use with liquid cosmetic products that removes excess liquid. Carluccio is designed to leave some amount of fluid on the rod and head of a cosmetic applicator when the applicator is withdrawn from the bottle unlike applicants.

As described, the structure of Carluccio is considerably different than that of the applicants. However, assuming a conical pipette tip as used in the applicant's invention (as suggested by the Examiner) was inserted into Carluccio the following would occur:

The conical pipette tip would enter opening 14a which is much larger than the pin-point dispensing end 114. As the conical wall 125 of the pipette tip 115 further penetrates the opening 14a, the wiper wall section 30 will rotate about the outside surface of the penetrating tip decreasing the wiper capability of the finger created by helical slot 34. As the wiping finger, enlarged by the increased diameter of the pipette tip, begins to retract about the smooth conical outside surface, the wiping finger can now only reach $\frac{1}{2}$ way around the conical shaped pipette tip. Because the wiping finger can now only reach $\frac{1}{2}$ way around the circumference of the pipette tip, the ability of the wiping finger can only then wipe $\frac{1}{2}$ of the surface. This leaves much of the non-calibrated fluid on the outside of the tip as it is withdrawn. Carluccio invention was designed this way to insure that when the applicator was inserted and removed, the wiping finger could never wrap itself completely about the applicator head. This was done to insure fluid was left on the applicator upon remove to allow the user to apply the mascara or nail polish.

This is in contrast to the applicant's invention which describes a one piece injection molded closure which incorporates a conical section with a spiral finger rotating at least one revolution from a substantially closed end and engineered to resiliently expand and contract about a tubular conical pipette tip. In doing so maintaining contact at all times with its outside surface while wiping and removing the fluid film or droplets from its surface as shown in Figures 16 and 17.

In conclusion, Carluccio teaches an alternative type of wiping mechanism that uses a lower wiping section 30 and wiper edge 32 to remove only a portion of the fluid that is attached to the applicator. **There is nothing in the 4 corners of this document to suggest or teach you that the wiping plug as claimed by Carluccio has at least one wiper finger rotating more than one revolution from a substantially closed end and is capable of wiping the entire outside**

surface of a pipette tip of all non-calibrated fluid as shown and describe by applicants invention.

Accordingly, Carluccio can not anticipate Claims 18 and 47. In addition it would not be proper to “combine” these disparate references since they are from unconnected fields and thus wouldn’t be obvious to use them together against this invention.

Leopardi – Pat. # 5,514,339

As suggested by the examiner, Leopardi, column 4, lines 13 – 20, teaches it is desirable to provide a wiping feature to remove excess liquid, such as blood, from the syringe (43).

Like Carluccio, Leopardi fails to disclose the invention as recited in claims 18 and 47. Leopardi does not disclose a conical resilient wiper section being configured to include at least one helically formed slot forming a wiper finger adapted to be resiliently held against the outside surface of a pipette tip inserted therethrough, said wiper finger including means to remove residue fluid from said outside surface of said pipette tip when said pipette tip is withdrawn axially through said wiper finger. Therefore, Leopardi cannot anticipate applicant’s invention.

Moreover, as the examiner has so implied, Leopardi invention is directed to a pierceable stopper used with a syringe type needle which can adequately protect the operator from accident contact with the blood sample during the transfer of blood during the removal stage. As illustrated in Figs 4 and 7. “The external element (42) of a twin-pointed disposable needle is introduced into the patient’s vein. Then the internal element (43) of the needle is introduced into the test tube (3) by perforating the pieceable stopper and bending the elastically yielding sectors (16) of the stopper (1).” Page 3, lines 60-66. In applications such as describe, the syringe is a positive fluid displacement device. This is because no air is allowed in the syringe and the syringe is used to remove blood from an individual. “The test tube thus sealed (Fig 1) maintains the predetermined vacuum, which has been provided herein, until the moment when it is necessary to take the patients blood” Page 3, lines 56-59. The pierceable stopper as describe by Leopardi maintains an air tight seal as the syringe is inserted and withdrawn thus wiping the blood from the syringe as so described by the examiner.

This is in direct contradiction to applicant's invention, in which a frustum shaped plastic pipette tip is used with a high precision air displacement pipetter, that is specifically engineered to transfer precision amounts of fluids from one location to another. Substituting the air-displacement pipetter for the positive fluid displacement syringe will not work. Even if you were able to pierce the wall of stopper 2A as does the syringe needle 43 does, the rubber sealable stopper material would form a seal about the outside diameter of the conical shaped pipette tip and form a seal. As you tried to withdraw fluid from this air seal test tube (3) the air-displacement pipetter could not overcome the vacuum that would be created within the test tube (3) created by the pipettors suction device as previously described in the summary section. This being the case, the fact that a positive displacement syringe needle could be wiped under these conditions could not anticipate that a conical shaped pipette tip would do the same. **This is shown to illustrate that a unworkable embodiment cannot anticipate an workable embodiment.**

It is also noted that wiping of the syringe needles surface does not solve the unrecognized problems associated with transferring of fluid previously describe by pipette tips:

- Affect the accuracy of the calibrated sample if they combine with the precise calibrated volume that is being dispensed from the inside of the pipette tip cavity
- Droplets can fall from the outside surface of the pipette tip while being transported in or out of the container;
- Droplets can migrate to the pipette tip's dispensing end and combine with the precision amount of internal calibrated fluid to affect the dispensing accuracy;
- Leads to cross-contamination or contamination in general, if any of the outside fluid were to contact any surface or thing (i.e. radioactive material or volatile fluids);
- Very small and precious any additional fluid that would be wasted by being attached to the outside surface of the pipette tip could become very costly and would allow fewer test specimens to be examined.

The pipette tip is not a syringe needle which is defined as a narrow tube fitted at one end with a piston used to inject fluids into, or extract fluids from body cavities. The syringe is not used to draw fluids in predetermine amounts with the accuracy and precision of less than 1.0 %. Thus the non-calibrated portion of fluid attached to a syringe needle is not of the same importance as that of a calibrate pipette tip.

The wiping mechanism as describe by Leopardi is primarily directed toward the need to reduce contamination associated with accidental contact with blood from patients. As shown above, contamination is only one of the many unrecognized problems that are addressed in the applicant invention. Leopardi does not disclose means for removing the non-calibrated residue fluid attached to a plastic frustum shaped pipette tip. The use of a pipette tip and thus the non-calibrated fluid that the applicants invention discloses is not address nor could not have been anticipated by Leopardi. Therefore, the rejection should be withdrawn.

Smith – Pat. # 5,513,768

The office action states Smith (Applicant is the inventor) teaches a cap for a container (12) comprising a locking cap (16) and a sealing cap (14) with a syringe port (54) and a sealing frustum (27). The embodiment of Figure 6 teaches the locking cap and syringe cap being connected to the container by hinges (22) and (38). The embodiment of Figure 13B teaches a threaded connection (188). Smith does not teach a wiping feature.

Applicants new invention includes a wiping cap, not a sealing cap (14), that is specifically engineered to incorporate a conical section with a spiral finger or fingers designed to resiliently expand and contract about a tubular conical pipette tip maintaining contact at all times with its outside surface while wiping and removing the fluid film or droplets from its surface. (Page 8, Lines 24-27).

The wiping cap is neither a sealing cap as described by previous issued patent (Smith '768) or would work as a wiping cap if a syringe as described in the Smith '768 was inserted into said wiping cap of applicant's new invention. The wiping cap of the Applicants invention is conical in design to accommodate frustum shaped standard pipette tips and not a tubular metal syringe as would be necessary to puncture said sealing cap in Smith '768. In addition, a standard plastic pipette tip could not puncture said sealing cap in Smith '768 nor access the fluid within container (12) without complete removal of said sealing cap in Smith '768.

There is no motivation to modify the structure of Smith '768 sealing cap (14) to accommodate the spiral fingers (90) require to resiliently expand and contract about a tubular conical pipette tip. The sealing member is configured for being inserted in the open end of a tubular member with the generally convex end wall positioned in the tubular member and bulging

in a direction away from the open end. With this construction, as the pressure in the tubular member increases, it tends to deflect and flatten the generally convex end wall, thereby causing the perimeter or rim of the end wall to expand radially outward and enhance the seal between the sealing member and the inner wall of the tubular member. As a result, the sealing capacity is increased when it is most needed, i.e., when high pressure within the tubular member develops. (Page 1, 44-61)

As can been seen, if the sealing cap (14) of Smith was replaced with the structure of the wiping cap of Carluccio as suggested in the office action, the spiral finger 30 rotated about the conical wall section 12 rotates less than one full turn as shown in Carluccio Figures 1 and 2. This would prevent the wiping finger 30 to fully encapsulate a pipette tip inserted therethrough since it would only reach $\frac{1}{2}$ the distance about the circumference of the pipette tip.

Motivation does not exist for modifying Smith '768 in view of Carluccio for the resulting combination would not arrive at the claimed invention for Carluccio does not teach a wiping finger that rotates more than one revolution being formed from a substantially closed end that removes non-calibrated fluid from the outside of a pipette tip.

Smith '768, Carluccio '298 and Leopardi '339 Do Not Contain Any Justification to Support Their Combination, Much Less in the Manner Proposed

With regard to the proposed combination of Smith '768, Carluccio '298 and Leopardi '339, it is well known that in order for any prior-art references themselves to be validly combined for use in a prior-art §103 rejection, the references themselves must suggest that they be combined, E.g., as was stated In re Sernaker, 217 U.S.P.Q. 1,6 (C.A.F.C. 1983):

“[P]rior art references in combination do not make an invention obvious unless something in the prior art references would suggest the advantages to be derived from combining their teachings.”

None of the references relied upon in the office action suggest the use of a conical shaped disposable pipette tip as is used with precision handheld pipetters as described in applicants invention. These disposable pipette tips are use for acquiring and transferring predetermine amounts of fluid samples with accuracy and precision below 1% unlike that of a

syringe type device used in Leopardi or an applicator brush used in Carluccio. These prior references solve unrecognized problems in different fields.

To better illustrate the field of invention, pipette tips are used in specific applications that require precision and accuracy not found in syringe or cosmetic use. As an example, because of the need to perform many tests from a limited amount of sample quantity, PCR was developed. The polymerase chain reaction (covered under U. S. Patents issued to CETUS Corporation), provides a method with which to produce many copies of a specific nucleotide sequence from a minute quantity of DNA. Dispensing amounts and false signals can be generated following PCR amplification **due to non-calibrated residue droplets that affect the accuracy during carry-over between existing pipette tips and air displacement pipetters**. As the scrutinizing of these and many more tests have become more demanding, the need to eliminate any and all non-calibrated fluid residue from these tips is imperative. **Even the smallest amounts of non-calibrated residue left behind on the surface of a pipette tip can invalidate, or skew the evaluations of new test samples causing hours or even days of laboratory research to be wasted.**

This is not disclosed in the teachings of Leopardi, which uses a syringe to draw blood into a test tube, whose only concern is potential contamination or contact with that blood. There is no mention of transferring precisions calibrated amounts of blood with accuracies of less than 1 % for testing or evaluation.

The office action states that Carluccio could be used to wipe excess material from a needle as that which is used in Leopardi. Leopardi discloses a needle but would not have motivated one of ordinary skill in the art to modify Carluccio to include means to wipe a needle or more particularly a plastic pipette tip. Even if motivation existed for this suggested the modification would not arrive at the claimed invention for Carluccio opening 14a is constructed to be the same diameter as the rod 18 in the relaxed or as molded condition. This diameter is much larger than head 22 which would be larger than a sized needle or syringe. There is nothing to suggest that Carluccio 14a diameter could wipe a needle. In fact, the small steel cores used to form the helical slot 34 in the injection mold would most likely relate to the size of a syringe needle. This being the case, the opening 14 is approximately 4-5 times the diameter of a standard needle and could not

wipe its surface free of fluid as thus could not anticipate applicant's invention. Therefore, the rejection should be withdrawn.

The structure of Carluccio has been shown not to be the same as that of the applicants. Carluccio wiping structures lacks a wiper finger that rotates more than one full revolution about its conical wiper section and thus would be incapable of wiping a pipette tip of all its non-calibrated residue fluid. This is due to the fact that the wiping finger 30 is incapable to fully encapsulate a pipette tip inserted therethrough since it would only reach $\frac{1}{2}$ the distance about the circumference of the pipette tip. Carluccio wiping finger begins from a large diameter opening 14a which is specifically engineered to mate with the rod 18 and not a substantially closed apex end as that of the applicant's invention. The opening 14a also includes wiper sedge 32 which adds strength and material to its opening to prevent it from being substantially closed. Thus even if motivation existed to modify or combine Carluccio, the resulting combination would not have arrived at the claimed invention. Carluccio cannot anticipate applicant's invention and the rejection should be withdrawn.

The office action suggest that it would have been obvious to modify Smith closure to add the wiping structure of Carluccio in view of the necessity to wipe a needle found in Leopardi. Even, if motivation existed for this modification, the resulting combination would not arrive at the claimed invention. Smith teaches a closure device with sealing cap but no wiping cap. Smith does not teach what Carluccio and Leopardi lack. Therefore, even if motivation existed for the suggested modification, the resulting combination would not arrive at the claimed invention. Accordingly, the rejection should be withdrawn.

Conclusion

In conclusion, it would not be proper to "combine" these disparate references since they are from unconnected fields and thus wouldn't be obvious to use them together against this invention. Carlucci whose invention relates to a mascara brush or nail polish applicator would not be obvious to be combined with a syringe as used in Leopardi to remove blood from a body cavity or Smith whose pressure responsive closure is used with centrifuge tubes in the medical laboratory industry.

In addition, Carlucci invention was never designed to remove all of the material from the brush or the head of applicator. Therefore, Carlucci could never anticipate the complete removal of all fluid of any device that would be used with his wiping invention as suggested by the office action.

Nevertheless, the examiner suggest that that the wiping structure of Carluccio is the same structure as that of the applicants invention, which is not , even though there is no written documentation to support such a teaching. Carluccio invention relies on the fact that it leaves material on the applicator head and does not remove all the fluid. With, this requirement, the helical slot (34) transcending wiper section (30) rotates less than full revolution only or approximately 270 degrees as shown in Figure 1 in the relaxed or unexpanded condition. Any brush or applicator head entering and expanding opening 14a will be sure to expand opening 14a and corresponding helical slot 34 that creates wiper wall 30 thus reducing the surface area that it can be wiped. The structure is designed to always wipe less than 270 degrees of the applicators surface to insure that Carluccio wiping device will never wrap completely around any device that enters said wiping plug. This is the intention of the embodiment of Carluccio in that it never removes all of the fluid material which contradicts that of the embodiment of the applicant's invention.

In addition, a major problem would occur if Carluccio invention was used with the applicants pipette tip. Because the wiper finger (30) of Carluccio would only reach say ½ way around the penetrating conical surface of the pipette tip, the wiper finger (30) will only direct the residue non-calibrated fluid from one side of the tip to the other because it can only wipe 180 degrees of the circumference of the diameter. The problem with this is that the remaining residue fluid would be pushed or moved to a much more concentrated area, piling up the fluid and possibly creating large droplets in the concentrated area. The enhanced fluid concentration would promote the creation of heavier fluid droplets on one side of the pipette tip. Some of the residue fluid would be pushed towards the apex end and would not be able to be wiped off due to the larger diameter 14a opening. The larger 14a opening of Carluccio is large and not resilient due to the additional wiper edge 32 thickness. This larger opening 14a would not allow the lower portion or wiper edge 32 to wrap itself about a small pin-point apex end of a withdrawn pipette tip. The

fluid would be more incline to migrate to the apex orifice end of the pipette tip which is where the calibrate fluid is dispensed from. These larger non-calibrated residue fluid droplets , which were formed by Carluccio wiping finger, would then combine with the calibrated fluid being dispensed causing possible invalidation of the particular test being conducted causing hours or even days of laboratory research to be wasted.

As shown, using Carluccio wiping invention would enhance the problems associated with fluid residue problem, thus it could not anticipate applicants invention which solves this problem. Applicant's invention solves a different problem than the reference, and such different problem is recited in the claims. *In re Wright*, 6 USPQ 2d 1959 (1988).

As described, Carluccio invention in combination with Smith and Leopardi is not the same structure nor combining the references would solve the same problem as is shown and described in the applicants invention in Figures 11, 12, 13 15, 16 and 17. Applicant's invention clearly states and shows the wiper fingers 90 rotate more than one full revolution and are formed from a substantially closed end 113 to insure the smallest of pipette tip dispensing ends 114 will be encapsulated. The wiping fingers 90 are created with at least one helical slot 112 that creates a squeegee like wiping action on the outside surface 125 of the pipette tip 115 removing the non-calibrated fluid 116 as the pipette tip is withdrawn axial from the wiper device. Therefore, even if motivation existed for the suggested modifications, the resulting combination as shown would not arrive at the claimed invention. The prior art fails to disclose or make obvious such a wiper design. Therefore amended claims 18 and 47 are respectfully in condition of allowance.

Claims 19-23 and claims 48-58 depends from independent claims 18 and 47 respectfully and are believed to overcome the 35USC103(a) rejection and define the invention in a patentable manner over the cited prior art. For all the above stated reasons, applicant submits claims 18-23 and 47-58 are all in a condition of allowance. Allowance of these claims is respectfully solicited.

Lastly, it seems unfair that the Examiner feels it is obvious to combine these disparate references or "nonanalogous art" since they are from unconnected fields and thus wouldn't be obvious to use them together against the applicant's invention. *In re Oetiker*, 24 USPQ 2d 1443 (Fed. Cir. 1992).



Conditional Request for Constructive Assistance

Applicant has amended the specification and claims of this application so that they are proper, definite, and define novel structure, which is unobvious. If for any reason this application is not believed to be in full condition for allowance, applicant respectfully requests the constructive assistance and suggestions of the Examiner pursuant to M.P.E.P 2173.02 and 707.07(j) in order that the undersigned can place this application in allowable condition as soon as possible and without the need for further proceedings.

Respectfully submitted,

Oct 31, 2006

Date

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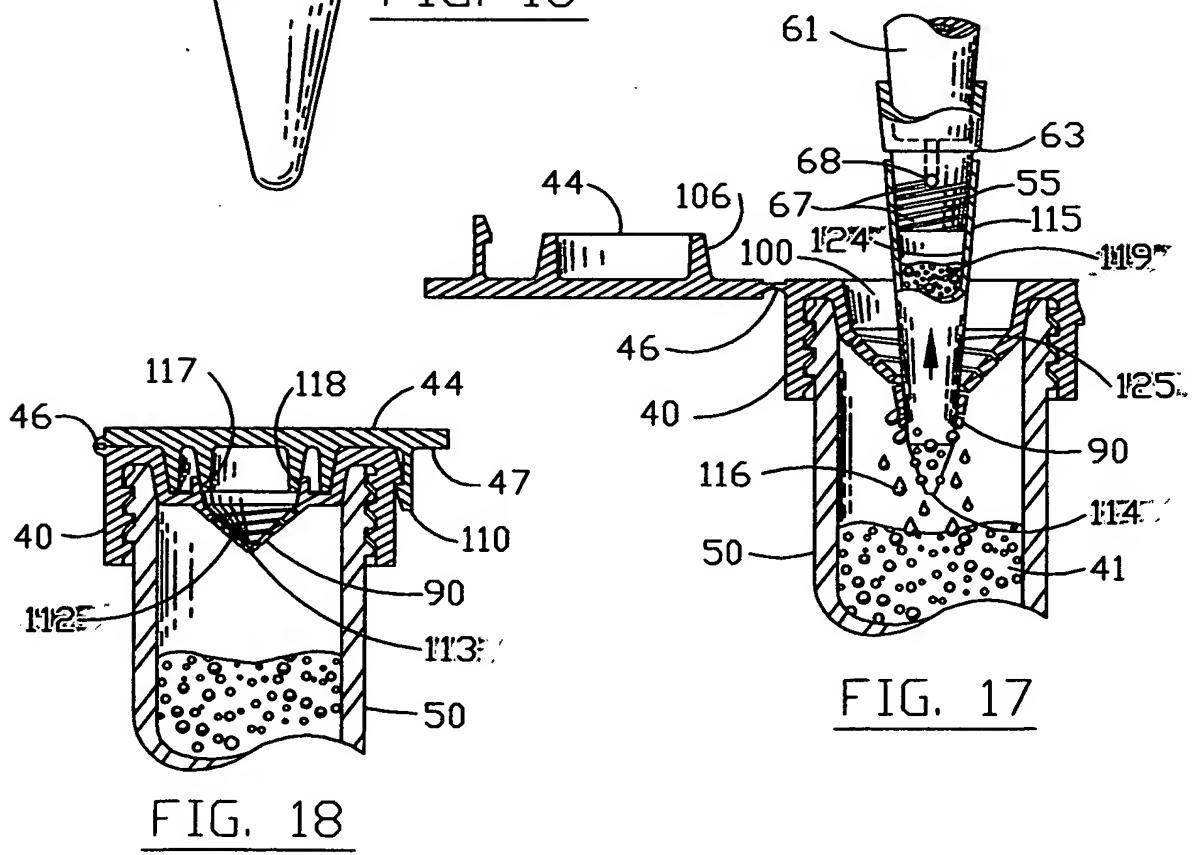
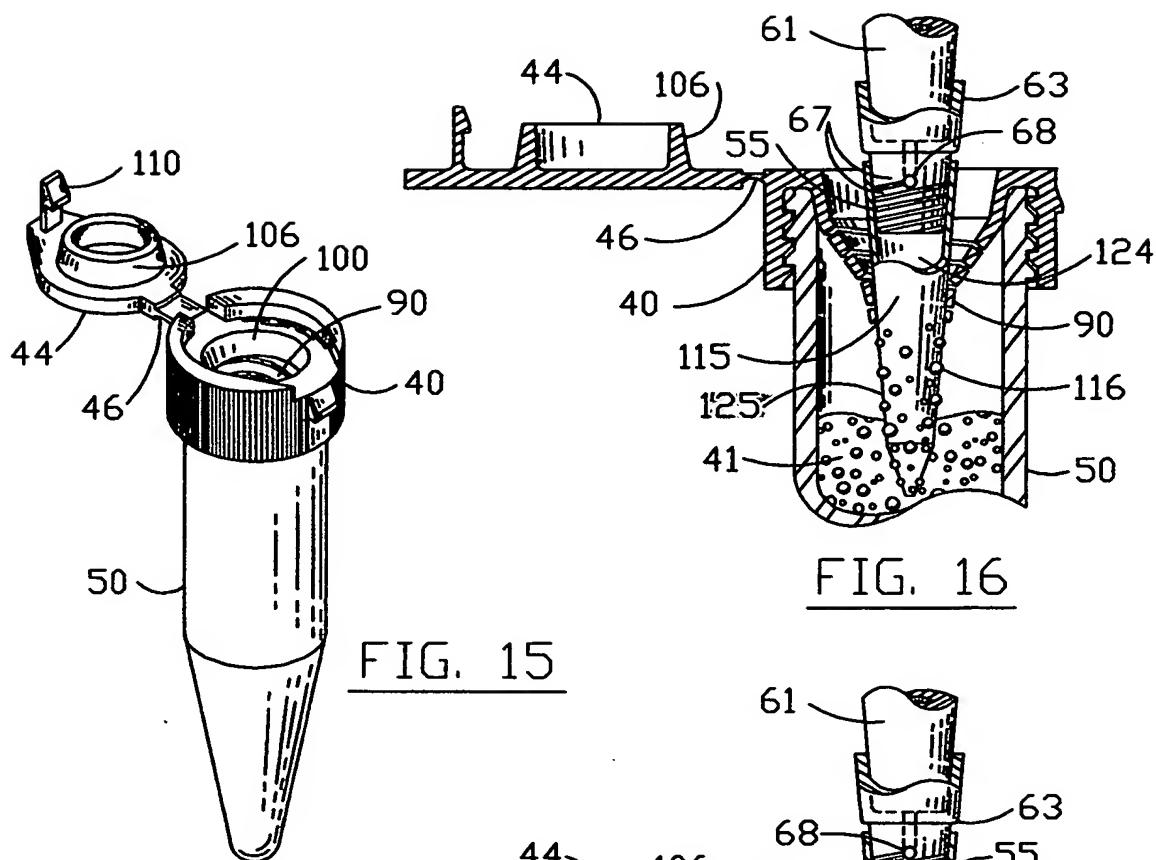
on: Oct 31, 2006

Date

By:

James C. Smith

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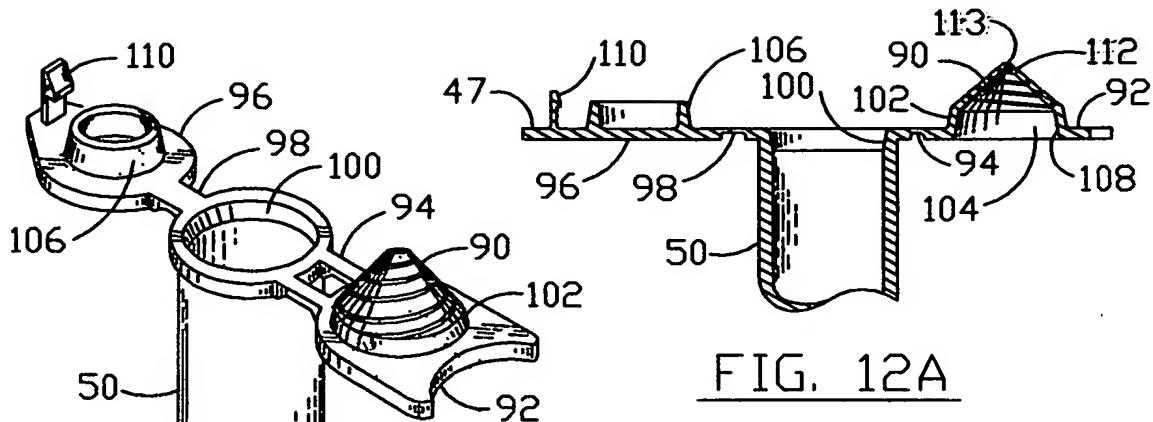


FIG. 12A

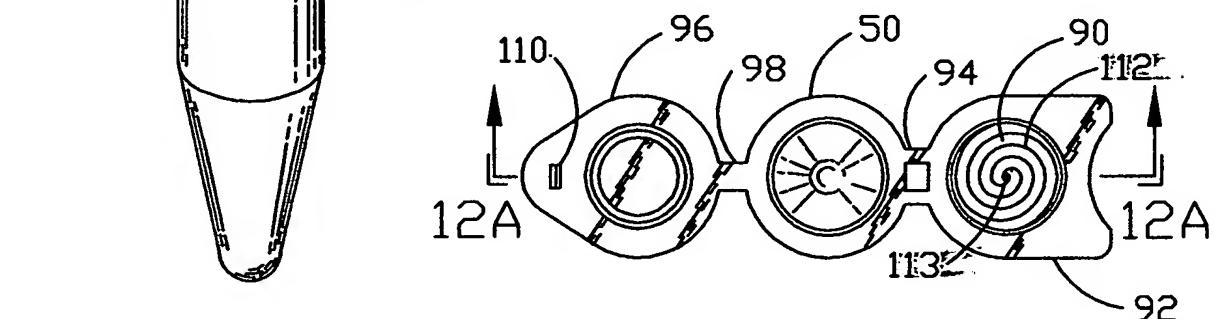


FIG. 11

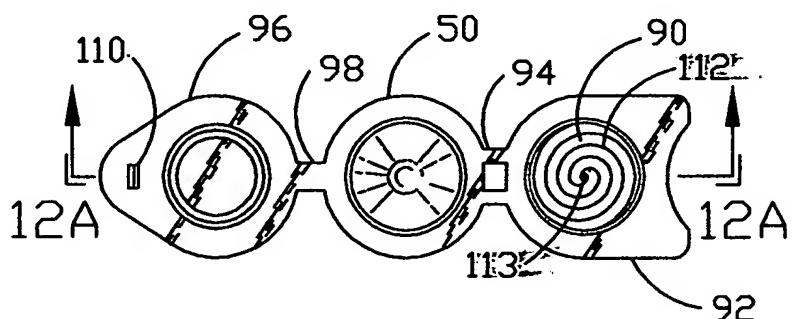


FIG. 12

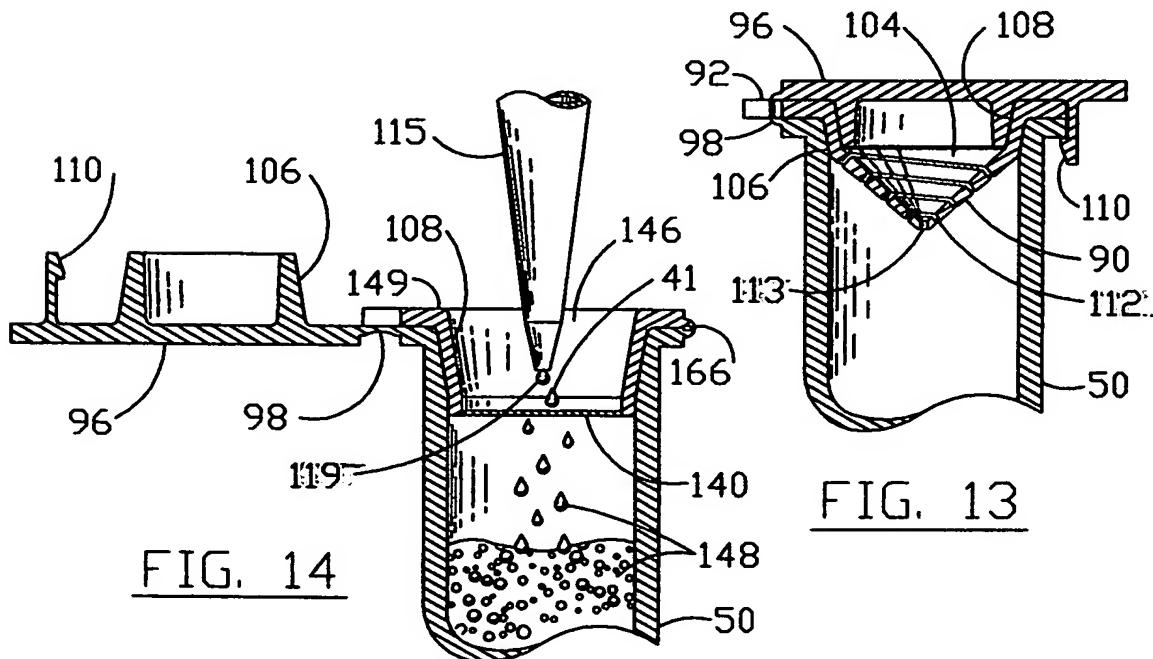


FIG. 13

FIG. 14

